DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 20, 2015

JJGC Industria e Comercio de Materiais Dentarios SA
c/o Mr. Kevin Thomas
PaxMed International, LLC
12264 El Camino Real, Ste 400
San Diego, California 92130

Re: K141777
Trade/Device Name: Neodent Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 15, 2015
Received: June 16, 2015

Dear Mr.Thomas,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141777

Device Name

Neodent Implant System

Indications for Use *(Describe)*

Zygomatic Implants are indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Zygomatic Implants are recommended for the posterior (pre-molar/ molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Zygomatic Implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
JJGC Indústria e Comércio de Materiais Dentários SA
Neodent Implant System
K141777

July 1, 2015

Manufacturer Name	JJGC Indústria e Comércio de Materiais Dentários SA Av. Juscelino Kubitschek de Oliveira, 3291 - CIC Curitiba, Paraná, 81270-200, Brazil Telephone: +55 41 2169 1003 Fax: +55 41 2169 1043
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Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 (858) 792-1235 Fax +1 (858) 792-1236 Email kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Neodent Implant System
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640
Product Code	DZE NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

Zygomatic Implants are indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Zygomatic Implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Zygomatic Implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

DEVICE DESCRIPTION

This submission includes threaded root-form dental implants designed for placement into the zygomatic bone with either an external hexagon abutment interface, or a Morse taper abutment interface. Both implant designs are provided with a thread major diameter of 4.4 mm at the coronal end of the implant (over a length of 10 mm), which tapers to a thread major diameter of 3.9 mm for the remaining implant length. Both implant designs are provided in multiple threaded lengths ranging from 30 mm to 52.5 mm. All implants are made of commercially pure titanium, Grade 4, conforming to ASTM F67, *Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700).*

This submission includes transepithelial abutments with external hexagon or Morse taper interfaces for connection to the zygomatic implants. The external hexagon abutments have a platform diameter of 4.1 mm and are provided in gingival heights of 3, 4, or 5 mm. The Morse taper transepithelial abutments also have a platform diameter of 4.1 mm and are provided in gingival heights of 1.5, 2, 3, 4, or 5 mm.

This submission also includes a Protection Cylinder that is used to protect the abutment during healing of the gingival tissue. The Protection Cylinder may be installed on either abutment design (external hexagon or Morse taper) with the corresponding Protection Cylinder Screw.

All transepithelial abutments, external hexagon transepithelial abutment screws, protection cylinders, and protection cylinder screws are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).*

All zygomatic implants are packaged assembled with the corresponding implant mount and provided sterilized by gamma irradiation. All transepithelial abutments, external hexagon transepithelial abutment screws, protection cylinders, and protection cylinder screws are provided sterilized by exposure to ethylene oxide.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility, engineering analysis, dimensional analysis, and dynamic compression-bending testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants.*

Clinical literature data were submitted in this premarket notification including reports of 45 subjects treated with a total of 90 predicate device (K070182) zygomatic implants in combination with 165 conventional dental implants, and 16 subjects treated with a total of 37 subject device zygomatic implants in combination with 58 conventional dental implants. All subjects were treated for rehabilitation of maxillary atrophy for restoration of aesthetics and chewing function. The subjects who received the predicate zygomatic implants were treated by a

delayed loading protocol in 44 of 45 cases (1 case of immediate loading); all subjects who received the subject device zygomatic implants had immediate loading (within 48 hours of surgical placement). Follow-up time periods for all subjects ranged from 6 to 36 months. For the subjects who received the predicate zygomatic implants, survival of the zygomatic implants was 100% and survival of the conventional implants ranged from 85.7 to 100%. Subjects who received the subject device zygomatic implants had 100% survival of all implants (zygomatic and conventional) after immediate loading at 12 months. These clinical data demonstrate the subject device is as safe, as effective and performs as well as the predicate device in the atrophic maxilla.

EQUIVALENCE TO MARKETED DEVICES

Neodent Implant System is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Nobel Biocare USA, LLC, Zygoma Implant, K070182;

JJGC Indústria e Comércio de Materiais Dentários SA, Neodent Implant System, K133510; and

JJGC Indústria e Comércio de Materiais Dentários SA, Neodent Implant System, K123022.

The primary predicate device is K070182. The reference predicate devices are K133510 and K123022. A comparison of the technological characteristics of the subject device and the primary predicate device K070182 is provided in the following table.

	Subject Device	**Primary Predicate Device**
Comparison	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K141777	Nobel Biocare USA, LLC Zygoma Implant K070182
Indications for Use	Zygomatic Implants are indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Zygomatic Implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Zygomatic Implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	Nobel Biocare's Zygoma implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function. The Zygoma Implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.
Implants		
Design	Threaded root-form implant to be used with mating abutments	External hex threaded root-form implant to be used with mating abutments
Platform (Ø)	4.1 mm	4.1 mm
Thread (major Ø)	4.4 mm tapering to 3.9 mm	4.4 mm tapering to 3.9 mm
Length, mm	External hex: 30, 35, 40, 45, 47.5, 50, 52.5	30, 35, 40, 45, 47.5, 50, 52.5
	Morse taper: 30, 35, 40, 42.5, 45, 47.5, 50, 52.5	n/a
Implant-Abutment Interface		
Type	External hex and Morse taper	External hex
Implant Head Angle	45°	45°
Implant Surface	Machined	Machined

	Subject Device	Primary Predicate Device
Comparison	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K141777	Nobel Biocare USA, LLC Zygoma Implant K070182
Abutments		
Platform (Ø)	4.1 mm	4.1 mm
Abutment Angle	0° (straight)	0° and 17°
Gingival Height	External hex: 3, 4, 5 mm	External hex: 2, 3, 5 mm
	Morse taper: 1.5, 2, 3, 4, 5 mm	n/a
Materials		
Implants	F67 commercially pure titanium, grade 4	Commercially pure titanium
Implant Mount	F136 Ti-6Al-4V ELI	Not stated
Implant Mount Screw	F136 Ti-6Al-4V ELI	Not stated
Abutments	F136 Ti-6Al-4V ELI	F136 Ti-6Al-4V ELI
Abutment Screws	External hex: F136 Ti-6Al-4V ELI	Not stated
Protection Cylinders	F136 Ti-6Al-4V ELI	n/a
Protection Cylinder Screws	F136 Ti-6Al-4V ELI	n/a

The subject device and the primary predicate K070182 have substantially equivalent indications for use, including restoration of patient esthetics and chewing function, and immediate loading when used with standard dental implants placed in the anterior region to support a fixed restoration. The implants of the subject device and the predicate device K070182 have similar designs, dimensions, materials, and machined surface finish. The abutments of the subject device have similar designs, similar dimensions, and are made from similar or identical materials as those cleared under K070182, K133510, and K123022. The subject device includes both external hexagon and Morse taper abutment-implant interface connections, whereas the K070182 predicate device includes only external hexagon connections. The subject device includes only straight abutments, whereas the K070182 predicate device abutments are provided in both straight and 17° angled designs. The subject device external hexagon abutments are provided in gingival heights of 3, 4, and 5 mm, whereas the K070182 predicate device external hexagon abutments are provided in gingival heights of 2, 3, and 5 mm.

The subject device has similar packaging and is sterilized using the same materials and processes as the predicate devices in K133510, and K123022.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and diameter, gingival height, and angle of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.